PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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COPY

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	28 July 2006 (28-07-2006)
Applicant's or agent's file reference 13453-62PCT	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA2005/000472	30 March 2005 (30-03-2005)	30 March 2004 (30-03-2004)

Applicant
CANADIAN BLOOD SERVICES ET AL

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide.*

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/CA	Authorized officer
Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	Carole Millaire (819) 994-6587

Form PCT/IPEA/416 (January 2004)

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 13453-62PCT	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/CA2005/000472	International filing date *(day/month/year)* 30 March 2005 (30-03-2005)	Priority date *(day/month/year)* 30 March 2004 (30-03-2004)

International Patent Classification (IPC) or national classification and IPC
IPC: ***A61K 39/395*** (2006.01) , ***A61K 39/00*** (2006.01) , ***A61P 37/00*** (2006.01)

Applicant
CANADIAN BLOOD SERVICES ET AL

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 13 sheets, as follows:
      [X] sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box.
   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))
      , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - [X] Box No. I Basis of the report
   - [X] Box No. II Priority
   - [X] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI Certain documents cited
   - [ ] Box No. VII Certain defects in the international application
   - [X] Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30 January 2006 (30-01-2006)	28 July 2006 (28-07-2006)
Name and mailing address of the IPEA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476	Authorized officer Qianfa Chen (819) 994-1374

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (Rules 12.3(a) and 23.1(b))

[ ] publication of the international application (Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

[ ] the international application as originally filed/furnished

[X] the description:

[X]	pages	1, 3-6, 8-26, 30 and 31		as originally filed/furnished
[X]	pages*	2 and 27-29	received by this Authority on	30 January 2006 (30-01-2006)
[X]	pages*	7	received by this Authority on	07 July 2006 (07-07-2006)

[X] the claims:

[ ]	pages			as originally filed/furnished
[ ]	pages*		as amended (together with any statement) under Article 19	
[X]	pages*	32-39 containing claims 1-62	received by this Authority on	11 July 2006 (11-07-2006)
[ ]	pages*		received by this Authority on	

[X] the drawings:

[X]	pages	1/14-14/14		as originally filed/furnished
[ ]	pages*		received by this Authority on	
[ ]	pages*		received by this Authority on	

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/figs

[ ] the sequence listing *(specify):*

[ ] any table(s) related to sequence listing *(specify):*

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. II Priority

1. [ ] This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

   [ ] copy of the earlier application whose priority has been claimed (Rule 66.7(a)).

   [ ] translation of the earlier application whose priority has been claimed (Rule 66.7(b)).

2. [ ] This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

The priority document has been found to provide support for claims 1-62.

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

[ ] the entire international application

[X] claims Nos. 1-32

because:

[X] the said international application, or the said claims Nos. 1-32
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

Claims 1-32 are directed to a method for treatment of the human or animal body by surgery or therapy, are not required to be searched nor is a written opinion required by this Authority under Rule 67.1 (iv) of the PCT. Regardless, this Authority has established an IPRP based on the alleged effect(s) or purpose(s)/use(s) of the product defined in claims 1-32.

[ ] the description, claims or drawings *(indicate particular elements below)* or said claims Nos.
are so unclear that no meaningful opinion could be formed *(specify)*:

[ ] the claims, or said claims Nos. are so inadequately supported
by the description that no meaningful opinion could be formed *(specify)*:

[ ] no international search report has been established for said claims Nos.

[ ] a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

[ ] furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

[ ] a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions; and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

[ ] the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

[ ] See Supplemental Box for further details.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-62	YES
	Claims		NO
Inventive step (IS)	Claims	1-62	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-62	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents (cited in the ISR):

D1: WO 99/03495 A1 (AVRAHAM, H. and GROOPMAN J.E.), 28 January 1999.

D2: WO 02/40047 A2 (LAZARUS, A. et al.), 23 May 2002.

D3: SONG, S. et al. Blood. 1 May 2003. Vol.101, No.9, pages 3708-3713.

Novelty and Inventive Steps

Claims 1-62 meet the criteria set out in Articles 33(2) and 33(3) of the PCT, because the closest prior art (D1, D2 or D3) does not teach a method, a composition or use thereof, for treating an immune thrombocytopenia or inflammatory arthritis, or for inhibiting platelet clearance in a patient by means of an in *vivo* antibody-antigen interaction without invoking the biological function of the antigen, wherein the administration of the antibody and/or the soluble antigens result in the selective binding of said antibody and said soluble antigen, and wherein said antigen is substantially soluble in vivo.

The closest prior art (D1, D2 or D3) describes the therapeutical application of monoclonal antibodies for treating auto-immune thrombocytopenic purpura (ITP) in a patient. Examples of the monoclonal antibodies include an anti-megakaryocytic cells antibody (anti-c-Mpl) in D1, anti-red blood cell antibodies (anti-CD24 and anti- TER-119) in D2 or D3, an anti-leukocyte antibody (anti-CD44) in D2 or D3, and a monoclonal antibody anti-CD16/32 in D3. Although the soluble form of each of the antigen proteins of c-Mpl, CD24, TER-119 , CD44 and CA16/32 of D1, D2 or D3 has been detected previously, the soluble form of the above antigen proteins only represents a small percentage of the antigen proteins in vivo. Majority of each of the above antigen proteins of D1, D2 or D3 are present on the cell surface and are not substantially soluble in vivo.

Industrial Applicability

Claims 1-62 have industrial applicability as defined under Article 33(4) of the PCT.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim Defects

Claims 1, 18, 33 and 48, when the expression "and/or" is "or", are broader in scope than the teaching of the description and do not comply with Article 6 of the *Patent Cooperation Treaty (PCT)*. The claimed method, composition and use thereof encompass subject matter that is not contemplated in the description by the applicant. The instant description on page 14, lines 17-19 indicates that ovalbumin (OVA, a foreign antigen) incubated with anti-OVA antibodies was capable of inhibiting ITP. However, the instant description on page 14, lines 20-26 also describes that "mice treated with soluble OVA alone (Figure 3A&B, 0.0 mg/mouse) or OVA + control IgG (data not shown) were not significantly protected from the development of immune thrombocytopenia. OVA by itself did not affect the platelet count at any dose tested (0.1 mg, 1 mg, 5 mg and 10 mg, data not shown). Similarly, all of the anti-OVA antibodies, in the absence of OVA, did not inhibit immune thrombocytopenia (data not shown)". This clearly suggests that neither a foreign antigen in the absence of an antibody specific thereto, nor an antibody specific for a soluble foreign antigen in the absence of the foreign antigen is capable of treating ITP. Therefore, a claim to a method or composition for treating ITP by administering an effective amount of an antibody specific for a soluble antigen, **or** a complementary soluble antigen thereof, without defining that the antibody specific for the soluble antigen is incubated with the soluble antigen prior to the administering, is not supported in the description as filed.